NORTH DAKOTA
DEPARTMENT *of* HEALTH

Health Alert Network

DEC. 15, 2009

HEALTH ADVISORY

Non-Safety Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for ages 6 months to 35 months) Vaccine in Pre-Filled Syringes

Summary

As part of its quality assurance program, Sanofi Pasteur, Inc., performs additional routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health- care providers to ensure that vaccines continue to meet required specifications. In recent testing of the amount of antigen in its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found four distributed lots of single-dose, pre-filled syringe pediatric (0.25 mL.) vaccine with antigen content lower than required potency levels. The manufacturer is conducting a non-safety related voluntary recall of these affected lots of vaccine.

Background

After performing these tests, Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the antigen content in one lot of pediatric syringes that had been distributed to providers was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that had fallen below pre-specified limits. This means that doses from these four vaccine lots no longer meet the specifications for antigen content.

Recommendations

While the antigen content of these lots is now below the specification limit for the product, CDC and FDA are in agreement that the small decrease in antigen content is unlikely to result in a clinically significant reduction in immune response among persons who have received the vaccine. For this reason, there is no need to revaccinate children who have received vaccine from these lots.

The following vaccine is being recalled:

- 0.25 mL pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25):
  - UT023DA
  - UT028DA
  - UT028CB
- 0.25 mL pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70):
  - UT030CA

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North Dakota providers received only one of the lots included in the recall. **Eight hundred doses of lot number UT023DA were distributed in North Dakota. According to the North Dakota Immunization Information System (NDIIS), 28 providers received vaccine from this lot number.**

The NDIIS shows that 424 doses of the recalled lot already have been administered. Please see the following table for a list of providers who received doses from the recalled lot of vaccine.

10 - BISMARCK-BURLEIGH PUB HLT
1081 - MEDCENTER ONE HOSPITAL
11 - FARGO CASS PUBLIC HEALTH
14 - UMDHU CROSBY
1516 - MINOT AIR FORCE BASE
18 - GRAND FORKS PUBLIC HEALTH
27 - CUSTER HEALTH - MORTON CO
3 - CITY-COUNTY HEALTH DISTRIC
300 - IHS-BELCOURT
302 - IHS-FT YATES
31 - LRDHU RAMSEY CO
34 - RICHLAND CO HEALTH DEPT
37 - SWDHU STARK
39 - CENTRAL VALLEY HEALTH
42 - DICKEY COUNTY HEALTH DIST
43- FIRST DIST HEALTH UNIT
44 - UPPER MISSOURI DIST HLTH
4831 - MID DAKOTA CLC KIRKWOOD
4852 - CENTER FOR FAMILY MED
4873 - MERITCARE CL JAMESTOWN
4894 - INNOVIS HLTH JAMESTOWN
4918 - MID-DAKOTA CLINIC
4921 - GREAT PLAINS CLINIC
4931 - VALLEY COMM HLTH CTRS
4943 - MERITCARE CLIN-WAHPETON
4959 - COMPREHENSIVE PED CARE
54 - ROLETTE COUNTY PHD
8271 - 319 MEDICAL CENTER

If the above providers still have vaccine on hand, it should be removed from the refrigerator and set aside (these doses will be wasted, so they do not have to be kept in cold storage). Providers should give these doses to the drivers who are delivering H1N1 vaccine. Providers who received doses from their local public health unit (Fargo Cass Public Health or Southwest District Health Unit), should return the doses to the local public health unit so the health unit can then return the doses to the North Dakota Department of Health or directly to the vaccine manufacturer.

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All vaccines are thoroughly tested prior to release and shipping to determine that they meet all manufacturer and FDA standards for purity, potency and safety. The affected vaccine met all specifications at the time of release. **CDC and FDA have determined that there are no safety concerns for children who have received this vaccine.** Sanofi Pasteur has discontinued distribution of the 0.25 mL syringes of H1N1 pediatric vaccines. The drop in antigen content below the required specification that is described here is specific to Sanofi Pasteur's pediatric H1N1 monovalent vaccine in 0.25 mL pre-filled syringes. The same vaccine packaged in other forms, such as 0.5 mL pre-filled syringes for older children and adults and multi-dose vials, continue to meet specifications.

The antigen content in the affected lots of vaccine is only slightly below the specification limit. The slightly reduced concentration of vaccine antigen found in retesting these lots is still expected to be effective in stimulating a protective response. There is no need to re-administer a dose to those who received vaccine from these lots. However, as is recommended for all 2009 H1N1 vaccines, all children younger than 10 should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. So, children younger than 10-years-old who have received only one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials is safe and effective vaccine for children. One difference between vaccine in pre-filled syringes and the multidose vials is that the multidose vials contain a preservative (thimerosal) to prevent potential contamination after the vial is opened. The standard dose for this preparation for administration to infants 6- to 35-months-old is the same as for the pre-filled syringes, 0.25 mL. For healthy children age 2 and older, the nasal spray (live, attenuated influenza vaccine) also is an option. The nasal spray vaccine is produced in single units that do not contain thimerosal.

For More Information:

- For questions and answers related to the recalled vaccine, visit www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm.
- Call CDC's toll-free information line at 800-CDC-INFO (800-232-4636) or TTY (888) 232-6348, which is available 24 hours a day, every day.

Further information will be distributed through the Health Alert Network (HAN) as needed and posted at www.ndhan.gov. Please contact the North Dakota Department of Health, Division of Disease Control at 701.328.2378 or 800.472.2180 with any questions regarding this issue.

Categories of Health Alert messages:

- *Health Alert conveys the highest level of importance; warrants immediate action or attention.*
- *Health Advisory provides important information for a specific incident or situation; may not require immediate action.*
- *Health Update provides updated information regarding an incident or situation; no immediate action necessary.*
- *Health Information provides general information that is not necessarily considered to be of an emergent nature.*

This message is being sent to local public health units, clinics, hospitals, physicians, tribal health, North Dakota Nurses Association, North Dakota Long Term Care Association, North Dakota Healthcare Association, North Dakota Medical Association, North Dakota EMS Association and hospital public information officers.